Subject: MolecuLight i:X Wound Care Device		Original Effective Date: 4/5/21
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Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The MolecuLight i:X Imaging Device is a handheld medical imaging device designed to detect bacteria in wounds based on known intrinsic fluorescence characteristics. The MolecuLight i:X illuminates the wound with 405 nm of light (violet) causing healthy tissue and bacteria to fluoresce. The device is comprised of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. MolecuLight i:X uses its patented

technology to enable real-time standard digital imaging and fluorescence imaging in wounds and surrounding healthy skin of patients as well as wound area measurements. This device is proposed to allow clinicians to diagnose and treat skin wounds, to view and digitally record images of a wound, measure and digitally record the size of a wound, and view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. The fluorescence image, when used in combination with clinical signs and symptoms, is intended to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone. The MolecuLight i:X device should not be used to rule-out the presence of bacteria in a wound and does not diagnose or treat skin wounds.

FDA: The MolecuLight i:X device was initially granted a de Novo classification (DEN180008) on February 16, 2018, followed by clearance for marketing (K191371) through the FDA Premarket Notification process on December 4, 2019. According to FDA labeling the device is indicated as a tool for clinicians to view and digitally record images of a wound, measure and digitally record the size of a wound, and view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.

POSITION STATEMENT

The Moleculight i:X device is considered experimental, investigational and unproven based on insufficient evidence in the peer reviewed literature to support its use in identification and management of wounds.

CONTINUATION OF THERAPY

N/A

LIMITATIONS

N/A

SUMMARY OF MEDICAL EVIDENCE

Overall, the evidence base for MolecuLight i:X is of low methodological quality and consists of only prospective multi or single center observational studies, and case series. There are no randomized controlled trials, meta-analysis or systematic reviews in the peer reviewed medical literature at the current time. Observational study designs and case series give low-quality evidence, sample sizes are small, and there are a limited range of outcomes. Additionally, there is a lack of evidence on wound closure times and the effect on antibiotic usage. The current evidence is insufficient to support the Moleculight i:X device when used for identification and management of wounds with bacterial burden or to prove safety and efficacy of the device as a tool for wound care management. A summary of the applicable studies is outlined below.

Le et al.; (2020) performed a prospective multicenter controlled study (n=350) from 14 outpatient advanced wound care centers across the United States. Wounds underwent assessment for clinical signs and symptoms (CSS) followed by fluorescence imaging (FL). Biopsies were collected to confirm total bacterial load. Three hundred fifty patients completed the study (138 diabetic foot ulcers, 106 venous leg ulcers, 60 surgical sites, 22 pressure ulcers, and 24 others). Results: Around 287/350 wounds (82%) had bacterial loads >10(4) CFU/g, and CSS missed detection of 85% of these wounds. FL significantly increased detection of bacteria (>10(4) CFU/g) by fourfold, and this was consistent across wound types ($p < 0.001$). Specificity of CSS+FL remained comparably high to CSS ($p = 1.0$). FL information modified treatment plans (69% of wounds), influenced wound bed preparation (85%), and improved overall patient care (90%) as reported by study clinicians. Innovation: This novel noncontact, handheld FL device provides immediate, objective information on presence, location, and load of bacteria at point of care. The authors concluded that the use of FL facilitates adherence to clinical guidelines recommending prompt detection and removal of bacterial burden to reduce wound infection and facilitate

healing. The study limitations included no randomization or comparison to alternative wound management techniques, prospective assessment, and study results included only a post-assessment survey to assess the impact of FL on treatment plan.

Chew et al.; (2020) evaluated the use of Moleculight i:X to identify infections in acute open wounds in hand trauma. Data were collected from patients (n=35) who attended the hand trauma unit over a 4 week period prior to having surgery. Wounds were inspected for clinical signs of infection and autofluorescence images were taken using the Moleculight i:X device. Wound swabs were taken and results interpreted according to report by microbiologist. Autofluorescence images were interpreted by a clinician blinded to the microbiology results. 31 patients were included and data collected from 35 wounds. 3 wounds (8.6%) showed positive clinical signs of infection, 3 (8.6%) were positive on autofluorescence imaging and 2 (5.7%) of wound swab samples were positive for significant infection. Autofluorescence imaging correlated with clinical signs and wound swab results for 34 wounds (97.1%). In one case, the clinical assessment and autofluorescence imaging showed positive signs of infection but the wound swabs were negative. The authors concluded that autofluorescence imaging in acute open wounds may be useful to provide real-time confirmation of bacterial infection and therefore guide management. Limitations of this study include a single-centre study restricts the reliability of findings, small sample size, no randomization or comparison to alternative wound management techniques.

Hurley et al.; (2019) conducted a single-center prospective observational study (n=33) in an outpatient plastic surgery wound care clinic. Patients had their wounds photographed under white and auto-fluorescent light with the imaging device. Auto-fluorescent images were compared with the microbiological swab results. RESULTS: A total of 33 patients and 43 swabs were included, of which 95.3% (n=41) were positive for bacteria growth. Staphylococcus aureus was the most common bacterial species identified. The imaging device had a sensitivity of 100% and specificity of 78% at identifying pathological bacteria presence in wounds on fluorescent light imaging. The positive predictive value (PPV) was 95.4%. The negative predictive value (NPV) was 100%. It demonstrated a sensitivity and specificity of 100% at detecting the presence of Pseudomonas spp. Authors concluded that he imaging device used could be a safe, effective, accurate and easy-to-use auto-fluorescent device to improve the assessment of wounds in the outpatient clinic setting. In conjunction with best clinical practice, the device can be used to guide clinicians use of antibiotics and specialized dressings. Limitations of this study include a single-centre study restricts the reliability of findings, small sample size, no randomization or comparison to alternative wound management techniques.

Raizmen et al.; (2019) conducted a clinical trial of (n=50) wounds to assess the accuracy, clinical incorporation and documentation capabilities of a handheld bacterial fluorescence imaging device (MolecuLight i:X). Benchtop wound models with known dimensions and clinical wound images were repeatedly measured by trained clinicians to quantify accuracy and intra/inter-user coefficients of variation (COV) of the imaging device measurement software. Wound dimensions were digitally measured and fluorescence images were acquired to assess for the presence of bacteria at moderate-to-heavy loads. Fluorescence imaging was implemented into the routine assessment of 22 routine diabetic foot ulcers (DFU) to determine appropriate debridement level and location based on bacterial fluorescence signals. According to the results, wound measurement accuracy was >95% (COV <3%). In the clinical trial of 50 wounds, 72% of study wounds demonstrated positive bacterial fluorescence signals. Levine sampling of wounds was found to under-report bacterial loads relative to fluorescence-guided curettage samples. Furthermore, fluorescence documentation of bacterial presence and location(s) resulted in more aggressive, fluorescence-targeted debridement in 17/20 DFUs after standard of care debridement failed to eliminate bacterial fluorescence in 100% of DFU debridements. The authors concluded that he bacterial fluorescence imaging device can be readily implemented for objective, evidenced-based wound assessment and documentation at the bedside. Bedside localization of regions with moderate-to-heavy bacterial loads facilitated improved sampling, debridement targeting and improved wound bed preparation. Limitations of this study include small sample size, no randomization or comparison to alternative wound management techniques.

Blumenthal et al.; (2018) conducted a pilot study (n=20) using the MolecuLight i:X camera in the management of burns to demonstrate the ability of the device to guide clinicians in their management of the burn (ie, detect, identify, and specify swabbing locations). Burn wounds were photographed under standard light and violet light illumination to compare presentations of obvious infection signs and symptoms. Microbiology swab samples were obtained to correlate any bacterial presence to the images. The fluorescence images were used to guide swabs to where the bacteria were congregating. Twenty patients were imaged. Four patients did not have bacterial contamination based on their images and swab results. Sixteen patients showed growth of Staphylococcus aureus, Pseudomonas aeruginosa, or other bacteria. Nine of the patients, by definition, had infections. These findings were correlated with the typical signs and symptoms of infection, the fluorescence images, and the microbiology results. The efficacy of the MolecuLight i:X is evident due to the microbiology results correlating to the images. The authors concluded that further research is being done to test the device in terms of being an early intervention tool and that early results and guidance of swab samples indicate that the MolecuLight i:X may be able to detect bacterial load before an infection and subsequent graft failure, thereby shortening lengths of hospital stay and improving overall healing. Limitations of this study include a single-centre study restricts the reliability of findings, there are no statistical analysis of results, small sample size, no randomization or comparison to alternative wound management techniques.

PROFESSIONAL SOCIETY GUIDELINES

There are no clinical practice guidelines or position statements from professional societies found at the current time.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (e.g. lower extremity)
0599T	each additional anatomic site (e.g. upper extremity) (List separately in addition to code for primary procedure) (Use 0599T in conjunction with 0598T)

HCPCS	Description
E1399	Durable medical equipment, miscellaneous

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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Peer Reviewed Publications

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13. Serena TE, Harrell K, Serena L, Yaakov RA. Real-time bacterial fluorescence imaging accurately identifies wounds with moderate-to-heavy bacterial burden. J Wound Care. 2019;28(6):346-357.

Professional Society Guidelines

14. National Institute for Health and Care Excellence. MolecuLight i:X for wound imaging. Medtech Innovation Briefing. (June 18, 2020. Available at: https://www.nice.org.uk/advice/mib212/chapter/Clinical-and-technical-evidence.

Other Resources

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16. Moleculight Corp. Pittsburg, PA. Manufacturing [website]. Accessed at: https://us.moleculight.com/
17. IRO Peer Review: [AMR]: Policy reviewed by practicing MD board certified in Board certified in Surgery General, Wound Care. 2/24/21. Additional references cited by the reviewer include:
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REVISION/REVIEW HISTORY:

4/5/2021: New Policy